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## **Administration tab**

## **Configure caAERS**

Click the **Administration** tab in the navigation bar. caAERS is installed with empty configuration information. You will need to enter information in the **Configure caAERS** task page to configure caAERS to work with a mail server and with caBIG Clinical Trials Suite (CCTS), if desired. All configuration is done on a single page.

Contents 1

The following table describes each field and notes whether it?s for mail server configuration or CCTS configuration.

Field Name	Description/Notes	Mail Server config	CCTS config
ESB queue URL	End point URL for accessing the CCTS ESB component		Required for ESB
LabViewer base URL	URL for accessing the CCTS LabViewer component		Required for Labviewer
Study Calendar base URL	URL for accessing the Patient Study Calendar (PSC) application (allowing you to place AEs on the calendar)		Required for PSC
Show debugging information	Only necessary if you?re interested in development		_
SMTP server	Address of your outgoing mail server, for example, smtp.gmail.com	Required	
SMTP password	Server password used to send mail; it is only necessary if the mail server requires authentication	Sometimes required	
SMTP port	Port used to send mail; this defaults to 25, but can be changed if you use a different port to send outgoing mail	Required	
SMTP user name	Server user name; it is only necessary if the mail server requires authentication	Sometimes required	
From address	Email address to be displayed in the ?from? field of all mail sent from caAERS; this does not have to be a valid email address	Not required, but useful	

**Note:** The **Show debugging information** is not related to either mail server or CCTS configuration. This field is for developers only.

### Configuring caAERS to work with a Mail Server

The caAERS application relies on sending e-mails? for alerts, reminders, and submission of some reports. In order to successfully send e-mails, caAERS must be set up to use a working Mail Server.

#### To configure caAERS to work with your mail server:

- 1. Click the **Administration** tab to go to the **Configure caAERS** task page
- 2. Enter the **SMTP server**. This is The address of the outgoing mail server (e.g.: smtp.gmail.com).
- 3. Enter the **SMTP password**. This is only necessary if the mail server requires authentication.
- 4. Enter the **SMTP port**, if different than 25.
- 5. Select **Yes** or **No** for **Secure SMTP?**.
- 6. Enter the **SMTP user name**. This is only necessary if the mail server requires authentication.
- 7. Enter the **From address**. The "from" address for all mail sent by caAERS. This address does not have to be a real e-mail address.
- 8. Click Save.

**Note:** If you do not provide information for your SMTP mail server, you will not be using caAERS full capabilities.

Note: You may need to restart the caAERS server before all the changes are recognized.

### Configuring caAERS to work with CCTS

If you plan to use caAERS as a tab in the caBIG Clinical Trials Suite, you will need to complete the steps outlined in this section. If you will be using caAERS as a standalone application, you can leave these fields

Configure caAERS 2

blank. To configure caAERS to work with CCTS:

- 1. Click the **Administration tab**.
- 2. Enter **ESB queue URL**. This is the URL for the enterprise service bus -- the value may not be applied until the application is restarted.
- 3. Enter the **LabViewer base URL**. This is the base URL for the LabViewer deployment to which this caAERS instance can link.
- 4. Enter the **Study Calendar base URL**. This is the base URL for the Study Calendar deployment to which this caAERS instance can link.
- 5. Click Save.

Note: You may need to restart the caAERS server before all the changes are recognized.

## Investigator

The Investigators tasks allow you to create Investigators and associate them to studies. It also allows you to search the system for Investigators to see if they are already in the system and/or associated to their studies. Investigators who are added to caAERS can receive email alerts and report submissions.

#### To Create/Edit an Investigator:

- 1. Click the **Administration** tab and click **Investigator** in the task menu.
- 2. Enter the **First Name**.
- 3. Enter the **Middle Name** if desired.
- 4. Enter the **Last Name**.
- 5. Enter the **Investigator number** if desired.
- 6. Enter the **Email address**.
- 7. Enter the **Phone** number.
- 8. Enter the **Fax** number if desired.
- 9. Enter the **Organization**. This is a pre-populated field. Enter the first few letters of the name of the Organization the Investigator is associated with and select it from the drop down menu that appears.
- 10. Select **Inactive** or **Active** from the **Status** drop down box.
- 11. If the Investigator works with another Organization, click **Add Organization** and repeat the steps above.
- 12. Click Save. If you entered information correctly into all the required fields you will see a

confirmation message stating that the system has Successfully saved the investigator.

**Note:** For an Investigator to be able to log into caAERS, you will need to also add the Investigator to caAERS as a Research Staff/User. To do this, please see the Research Staff section of this guide.

### **Searching for an Investigator**

- 1. Click the **Administration** tab and click **Investigator** in the task menu and then click **Search Investigator** in the steps menu.
- 2. In the **Investigator Criteria** box enter in the First Name, Last Name, and/or the Investigator number field and then click **Search**.

Investigator 3

Note: You can also leave the fields blank and click **Search** to list all Investigators.

- 3. The Investigators available will be listed in the bottom of the page. You can sort the search results by entering the appropriate information in the **First Name**, **Last Name**, **Middle Name** or **NCI Institute Code** text fields top of each column and then clicking the **Filter** button in the top right hand of the **Search Results** box.
- 4. Click on the **First Name** of an investigator in the search results to view and/or edit the investigator profile.

### **Research Staff**

Click the **Administration** tab and click **Research Staff** in the task menu. All users of the caAERS system have accounts, although their access rights vary. The Research Staff Page allows you to create the user accounts and assign their roles. Access to the different areas of caAERS is controlled by the user roles and each user can be assigned to multiple roles.

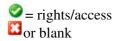
#### These roles are:

- Subject Coordinator? Provides access to the Adverse Events, Studies, and Subjects tabs; the user can document AEs and create reports, studies, and subjects
- **Study Coordinator**? Provides access to the Studies tab; the user can review studies, AEs, and expedited reports
- Adverse Event (AE) Coordinator ? Provides access to the Adverse Events tab; the user can view and report AEs for studies they are assigned to
- **Site Coordinator**? Provides access to the Adverse Events, Studies, Rules, and Administration tabs; the user can report AEs, create studies, set up rules, and have access to administrative features of the application.

**Note:** The only tasks the site coordinator doesn?t have access to is documenting AEs.

Each role provides access to different functions in caAERS. When you log in to

caAERS, you will only see the tabs and tasks that you have role authority for. The following table shows what functionality each role has access to.



= no rights or access If you feel you have not been assigned to the proper user role(s), contact your

caAERS Site Coordinator or System Administrator.

AE Module	AE Coordinator	Study Coordinator	Subject Coordinator	Site Coordinator	System Admin
AE Module tab	<b>②</b>	<b>②</b>	<b>②</b>	<b>②</b>	
<ul> <li>document AEs</li> <li>evaluation periods</li> <li>expedited reports</li> <li>link from Manage report</li> </ul>	(for assigned studies)	**	(for assigned studies)	**	<b>&gt;</b>

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(when now AEs have been documented yet)					
edit AEs  • evaluation periods • expedited report • Links from Manage reports (Submit, Amend, Withdraw, and report to PSC; hyperlink of expedited report and evaluation period)	(for assigned studies)	**	(for assigned studies)	<b>::</b>	<b>②</b>
View manage reports  • view details of evaluation periods, expedited reports, and routine AEs • Print PDFs of expedited reports • View expedited report in AdEERS	(for assigned studies)	(for assigned studies)	(for assigned studies)	<b>Ø</b>	<b>Ø</b>
Studies Module	AE Coordinator	Study Coordinator	Subject Coordinator	Site Coordinator	System Admin
Studies Module tab	×	<b>Ø</b>	0	0	0
Create Study	×	0	X	0	0
Edit Study	×	0	×	0	0
View Study	×	0	(for assigned studies)	0	0
Search Studies	×	0	(for assigned studies)	0	0
Subjects Module	AE Coordinator	Study Coordinator	Subject Coordinator	Site Coordinator	System Admin
Subjects Module tab	**	<b>Ø</b>	<b>②</b>	<b>②</b>	0
Create and Assign Subject	×	×	(for assigned studies)	<b>&gt;</b>	0
Assign a Subject to a Study (Subject already created)	*	(for assigned studies)	(for assigned studies)	<b>&gt;</b>	<b>Ø</b>
View Subject	E	(for assigned studies)	(for assigned studies)	0	0
Search Subject	×	(for assigned studies)	(for assigned studies)	<b>Ø</b>	0

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Advanced Search Module	AE	Study	Subject	Site	System
	Coordinator	Coordinator	Coordinator	Coordinator	Admin
Advanced Search module tab	<b>Ø</b>	<b>Ø</b>	<b>Ø</b>	<b>Ø</b>	<b>Ø</b>
Study Search	×	<b>Ø</b>	(for assigned studies)	<b>Ø</b>	<b>②</b>
Subject Search	X	(for assigned studies)	(for assigned studies)	<b>&gt;</b>	0
Expedited Report Search	(for assigned studies)	(for assigned studies)	(for assigned studies)	0	0
Rules module	AE Coordinator	Study Coordinator	Subject Coordinator	Site Coordinator	System Admin
Rules Module tab	×	*	*	<b>②</b>	
Create Rule	×	×	×	<b>②</b>	0
Edit Rule	*	×	×	<b>②</b>	<b>②</b>
Create Report Definition	*	×	×	<b>②</b>	<b>②</b>
<b>Edit Report Definition</b>	×	×	×	<b>②</b>	<b>②</b>
View Report Definition	*	×	×	<b>②</b>	0
Admin module	AE Coordinator	Study Coordinator	Subject Coordinator	Site Coordinator	System Admin
Admin Module tab	*	×	×	<b>②</b>	<b>②</b>
create/edit/search Organization	X	×	×	0	0
create/edit/search Research Staff	×	X	X	<b>Ø</b>	0
configure caAERS	×	×	×		
create/edit/search Investigator	×	×	×	0	0
Import MedDRA	×	×	×	<b>②</b>	0
IND	*	EK .	EK .	<b>②</b>	0
Password Policy	*	EK .	EK .	<b>②</b>	0
Import Study, Subject, Research Staff, Investigator	×	X	X	<b>②</b>	<b>&gt;</b>

## **Import**

Studies, subjects, routine AEs, Investigators and Research staff can be imported into caAERS. If you have previously used other applications and databases to maintain this information you can import it instead of manually entering it. To import studies, subjects, Routine AEs, Investigators or Research staff create valid XML files from the information in your existing application/database. Create separate XML files for each type of data (studies, subjects, and AEs). Combining everything into a single XLM file will cause the import to fail. To review copies of the XSD files and sample XML files, go to

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https://gforge.nci.nih.gov/svnroot/caaersappdev/docs/import/1.5.

### To import:

- 1. Create an XML file containing the information you want to import.
- 2. Click the **Administration** tab and click **Import** in the task menu.
- 3. Click on Import Study/Protocol, Import Subject, Import Routine AEs, Import Investigator or Import Research Staff.
- 4. Click **Browse** to locate and select the XML file that contains the information.
- 5. Click Save or Save & Continue.
- 6. The system will validate the XML file and show a synopsis of what will be imported on the **Review** and **Submit** page; if the information looks correct, click **Save**; depending on the size of the file, this could take minutes to hours to complete
- 7. To verify the information imported correctly, use the search task in the **Adverse Events**, **Studies**, or **Subjects Tab**.

## **Import MedDRA**

The caAERS installation includes the CTC v2 and CTCAE v3 vocabulary. CTC is a free open-source medical vocabulary that can be used to code clinical studies. An alternative to CTC is MedDRA terminology. If your organization uses MedDRA, the vocabulary can be imported into the application. Currently, only MedDRA versions 9.0, 9.1, and 10.0 are supported. MedDRA is stored in several ASCII (.asc) files. If the file format you try to import does not mach the allowed format, the import will fail.

### To import MedDRA files:

- 1. Locate the folder where MedDRA is stored.
- 2. Click the **Administration** tab and click **Import MedDRA** in the task menu.
- 3. Enter the full path to the folder that is located on the server which contains the files to be imported click **Import MedDRA**. **Note:** The MedDRA files and folder must be **located on the server** that caAERS is installed on. You cannot import files from a folder that is located on the "client side" or desktop computer.

### IND#

Investigational new drugs (IND) can be added in caAERS for use in studies. By adding the IND information, adverse events related to a particular IND can be tracked more efficiently.

### **Creating an IND**

- 1. Click the **Administration** tab and click **IND**# in the task menu
- 2. Enter the IND#
- 3. Click the IND held by? drop down box to select Organization or Investigator.
- 4. Enter the **IND Holder**. This is a pre-populated field. Enter the first few letters of the name of the IND Holder and select it from the drop down menu that appears.
- 5. Click Save.

#### **Searching for an IND**

Import MedDRA 7

- 1. Click the **Administration** tab, click IND# in the task menu and click **Search IND**# in the steps menu.
- 2. Enter search criteria in the **IND** # and/or the **IND holder** field and then click **Search**. **Note:** You can leave the fields blank and click **Search** to list all INDs.
- 3. The INDs will be listed in the bottom of the page. You can sort search results by entering appropriate information for IND # and/or Sponsor Name in the text fields at the top of each column and clicking the Filter button the top right corner of the Search Results section.

## **Organization**

An Organization can be a site, a sponsor, or any institution associated with clinical trials and is a required field to add investigators and research staff. caAERS includes a large list of organizations as part of the basic install. If needed, additional organizations can be added to the list.

**Searching for an Organization** Since Organizations are included in the installation, you should first search caAERS for the organization before you add it.

#### To search for an organization:

- 1. Click the **Administration** tab, click **Organization** in the task menu, click **Search Organization** in the steps menu to bring up the Search Organization page
- 2. Enter search criteria in the Name and/or the NCI Identifier field and then click **Search**. **Note:** You can leave the fields blank and click **Search** to list all Organizations.
- 3. The Organizations available will be listed in the bottom of the page. You can sort the search results by entering the appropriate information in the **Name** and/or the **NCI Identifier** text fields at the top of each column and then clicking the **Filter** button in the top right corner of the **Search Results** section.
- 4. To view and/or edit an organization listed in the search results, mouse over the Name and click on it.

#### **Create an Organization**

- 1. Click on the **Administration** tab and click **Organization** in the task menu to open the **Create Organization** page.
- 2. Enter the Name
- 3. If you want to provide additional details, enter the **Description**
- 4. Enter the **NCI Identifier**. The NCI Identifier is the primary id used by NCI and can be found at <a href="http://ctep.cancer.gov/forms/Organization Codes.txt">http://ctep.cancer.gov/forms/Organization Codes.txt</a>
- 5. Click **Save** to create the organization.

## **Configure Password Policy**

caAERS allows you to create specific rules regarding the creation of user passwords. This creates a more secure environment and allows you to control the level of security for user passwords.

#### To configure the password policy:

- 1. Click the **Administration** tab and click **Configure Password Policy** in the task menu.
- 2. Enter **Maximum password age** ? this determines how long a user can keep a password before having to reset it.
- 3. Enter Number of allowed failed login attempts.

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- 4. Enter the **Lockout duration** ? this determines how long a person is locked out of the system after entering the wrong password the number of allowed times.
- 5. Enter the **Minimum password age**? this prevents a user from recreating their password numerous times in a row to go back to the same password.
- 6. Enter the **Password history size**? this determines how many past passwords you keep in the system for a user.
- 7. Enter Minimum password length.
- 8. Select the appropriate checkboxes for the **Complexity Requirement**.
- 9. Enter largest substring of username allowed? this prevents users from having their password too similar to their user name.
- 10. Click Save.

### **Rules Tab**

## Manage & Create Rules

To create and manage rules click the **Rules** tab in the navigation bar.

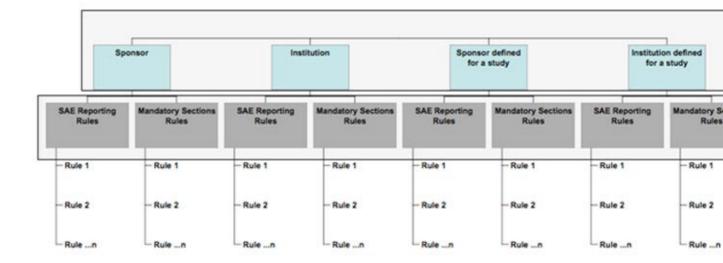
There are four categories (or Rule Levels):

- Sponsor
- Institution
- Sponsor defined for a study
- Institution defined for a study

Each category can have multiple rulesets associated to it. At this time, there are two rulesets:

- SAE Reporting Rules
- Mandatory Sections Rules

Each of these rulesets can then have one or more rules associated to it. The following diagram shows this visually.



**For example:** If you are entering rules for the Sponsor Wake Forest, it could have an SAE Reporting Ruleset and a Mandatory Sections Ruleset, each with their own rules. Wake Forest may also have specialized rulesets for a specific study. Another Sponsor, DCP might only have the SAE Reporting Ruleset, and it?d be completely separate from Wake Forest.

#### To manually enter rules:

- 1. Select Category (Rule Level)
- 2. Select Ruleset
- 3. Create Rules
- 4. Review
- 5. Enable Rule Set

#### 1. Select Category

The first step for creating rules is to determine what category the rule falls in. Click the Rules tab in the navigation bar. As discussed in the introduction, there are four different categories to choose from:

- Sponsor
- Institution
- Sponsor defined for a study
- Institution defined for a study
- 1. Make a selection in the **Rule Level** section and the associated text field will appear on the page.
- 2. Enter information into the fields that appear. This may mean you?re entering a Sponsor or an Institution, with the possibility of entering a study.

**Note:** These are pre-populated fields. Enter the first few letters of the name of the **Sponsor** or **Institution** you are looking for and select it from the drop down menu.

3. Click Continue.

#### 2. Select Ruleset

The next page allows you to select the rulesets. It will display any existing rulesets associated with the rule level you selected. You have the option to select an existing ruleset or create a new ruleset.

#### **Existing Rulesets**

If you chose Sponsor defined for a study or Institution defined for a study, and you?ve already went through the process for Sponsor or Institution rules, some of the information may already exist.

**Note:** Remember, there are only two Rulesets to choose from, and you can only have one of each type. So, if there?s an existing Ruleset, any changes you make to the rules will override the Ruleset that already exists. Making changes to an existing Ruleset will not create a separate Ruleset.

- 1. Select the radio button next to an existing Ruleset in the **Rule Set** section.
- 2. Click Continue.

If no rulesets exist you will need to create a Rule Set.

#### 3. Create Rules

- 1. Click the **Create Rule Set** button.
- 2. Select one of the options from the **Rule Set Name** field.
- 3. Click the **Continue** button.

On the **Rules** page you can add rules to the Ruleset by clicking the **Add Rule** button in the right hand side of the page.

**Note:** If you chose an exiting Ruleset for the Sponsor or Institution category, there may be rules already associated with it. **Any changes you make will override what currently exists, not create a separate Ruleset.** 

**Note:** If you chose an existing Ruleset for the Sponsor defined for a study or Institution defined for a study category, the Rulesets for the corresponding Sponsor or Institution category are automatically included so you do not have to enter the information again. You can then add or delete rules.

**Important:** Changes you make by following these instructions only apply to the ruleset associated with the Sponsor defined for a study or Institution defined for a study category. Changes do not apply for the original Sponsor or Institution category.

- 1. Click **Add Rule** in the right hand side of the page and a form will appear that will allow you to define the rules that go with the Ruleset. There are four drop down boxes.
- 2. **Select Domain Object:** Select Adverse Event, Study, or Report Definition from the Domain Object drop down menu.
- 3. **Select Field:** Select an option from the Field drop-down menu. The options available are dependent on what was selected as the Domain Type.
- 4. **Select operator:** Select an option from the Operator drop-down menu. This menu will always list Equal to and Not Equal to, and depending on your previous selections, may also list Greater Than or Equal To and Less Than or Equal To.
- 5. **Select Value:** Select a value from the Value drop-down menu. The options will vary based on the Domain Object and Field selected.
- 6. If there are additional conditions you want to assign to this Rule, click on the Plus ( b) icon and repeat the steps above.

**Note:** All of the conditions listed must be met for the Rule to be completed and saved in the system. If you do not require all the conditions to be met, create a separate Ruleset.

**Note:** You can remove conditions by clicking on the Red x icon.

Continue to step 7 if there are no additional conditions to assign to this Rule.

- 7. Select an option from the **Action** box.
- 8. To continue, click the **Continue** button. To add another rule, click **Add Rule** and repeat the steps above. To delete a rule, click the icon, **X**, in the right-hand corner of the rule.

#### 4. Review

The Review page allows you to review and verify the information before saving the ruleset. Click the **Save** button to save the rule you?ve created, or click **Back** to go back and make changes.

#### 5. Enable Rule Set

All new rules sets are given the status of Not Enabled. Go to the **Action** column and click **Enable**. Or you can leave the status as Not Enabled and return to the **List Rules** task page at a later time to enable it.

### **List Rules**

The List Rules page displays all Rules that exist in the system. For each Ruleset, you can view the Level, the Organization, the Study, and the Status. You can also choose to Enable, Disable, or Delete the Ruleset. In addition, you can Export/Download the Ruleset to an XML file.

#### • Enabling Rulesets

Rulesets may have a Status of Not Enabled. To enable a ruleset, click **Enable** from the **Action** column.

#### • Disabling Rulesets

If you don?t want a ruleset to be active anymore, you can disable it by clicking **Disable** from the **Action** column.

#### • Export/Download Rulesets

You have the ability to export the ruleset to XML files. To export a ruleset, click **Export/Download** from the **Action** column.

#### • Deleting Rulesets

If the ruleset is no longer valid, you can delete it by clicking **Delete** from the **Action** column.

## **Import Rules**

You can import existing rulesets into caAERS. This is an easier and faster way to set up rules in caAERS. At present, there is a small set of existing rules covering the baseline reporting rules for most CTEP sponsored trials. New rulesets are being developed and added to this library. Copies of these existing rulesets can be obtained from the caAERS Gforger project site,

https://gforge.nci.nih.gov/plugins/scmsvn/viewcvs.php/docs/rules/1.5/?root=caaersappdev.

### To import rulesets:

- 1. Click the **Rules** tab and click **Import Rules** in the task menu.
- 2. Click **Browse** to locate and select the XML file that contains the ruleset.
- 3. Click Import.
- 4. If the import was successful, you will receive the message ?Rules imported successfully?. If it was not successful, you will receive a message telling you to contact the system administrator.

List Rules 12

**Note:** Although it is possible to create rulesets for importing using an XML authoring tool, we recommend against it. Rulesets imported into caAERS should be obtained from the caAERS ruleset library or else they should be created in caAERS using the Ruleset XML export feature.

## **Configure Reporting Definitions**

When you first install caAERS and import the XML Rules files we provide, caAERS will create skeleton Reporting Definitions for CTEP reports. If the rules state that a report is required, a skeleton Report Definition will be created. These skeleton reporting definitions do not include all the necessary information. For example, it won't have the following:

- Information to electronically submit reports to AdEERS
- Notifications that are sent o interested parties
- Defined mandatory fields to assist the users with creating expedited reports.

**Note:** caAERS will not create skeleton Report Definitions for DCP reports. If you import the DCP rules before you create the Report Definitions, you will want to delete and re-import the rules to guarantee they function correctly.

<u>This spreadsheet</u> provides a matrix on how to configure the Reporting Definitions. Some note about the spreadsheet:

- The first tab of the spreadsheet includes information for the first two tabs of the setup process, including details and delivery details.
- The second tab provides information for the third step of the process, the mandatory fields.
- The third tab provides the notifications we've set up for the reports.
- The file displays the information for the AdEERS staging system. To submit an expedited report to this site, the study must already be entered in the staging system.
- Some of the information listed in the spreadsheet is suggested data while other sections are 100% define. View the page/section column to determine what can be modified (Delivery Details for example) and what must be entered as displayed (Mandatory Fields for example).

In addition, if your organization has other reporting requirements, you can use the spreadsheet as a reference sheet to help configure the report definitions.

To configure reporting definitions:

- 1. Log in to caAERS using an account with access to the Administration area
- 2. Go to Rules
- 3. Select List Reporting Definitions
- 4. Select a Report and modify the information

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## **Create Report Definition**

Click the **Rules** tab and click **Create Report Definition** in the task menu. Report definitions are the backbone of caAERS, identifying what information is required in a report and who receives the report. The report definitions you create will be used when defining rules for your rulesets.

### Creating a report definition is done in five steps:

- 1. Basic Details? enter the general information for the report
- 2. Delivery Details? enter who receives the report
- 3. Mandatory Fields? enter what information is mandatory
- 4. Notifications? enter reminders for the report
- 5. Review? review the settings for the report

#### 1. Basic Details

The Basic Details page defines the general information for the report. A red asterisk \* next to a field means it is required information.

- 1. Enter the organization in the **Organization** field. This is a pre-populated field. Enter the first few letters of the name of the Organization you are looking for and select it from the drop-down menu that appears.
- 2. Enter a name in the **Name** field.
- 3. Enter a name in the **Display Name** field. Keep the name simple but descriptive.
- 4. Enter a **Description** if you want to add more information for the report.
- 5. Select Yes or No for Amendable. This field defaults to Yes, which means the report can be added.
- 6. Select **Yes** or **No** for **Report is expedited?**.
- 7. Make a selection from the **Report Format** drop down list. Format choices are: caAERS XML, AdEERS PDF, MedWatch 3500A PDF, DCP SAE PDF, CIOMS PDF and DCP Safety Report PDF. **Note:**The selection of Mandatory fields you can select from will vary in the following **Mandatory Fields** task page based on the Report Format you select.
- 8. Select **Yes** or **No** for **Attribution** required. This field defaults to No. If you change it to Yes, it means that any time an AE is reported on, it must be related to an attribute.
- 9. Select a value for **Time Scale UOM** (unit of measurement) from the drop down box. This value tells you the measurement of time before the report is due.
- 10. Enter a number for **Time until report due**. This number is associated with what you selected for Time Scale UOM, and determines the specific measurement for when the report is due. For example, if you chose Days for Time Scale UOM, and then entered 5, you?re setting the report to be due 5 days after you document the AE.
- 11. Click **Continue** to go to the next step.

**Warning:** If you navigate from this page to a different area of caAERS without completing the entire report definition process, all information will be lost, even if you have clicked Continue.

#### 2. Delivery Details

The delivery details allow you to setup recipients of this report. The report can be sent to a specific email address, a role, or a URL. Reports sent to email addresses and roles are sent as PDF files while reports sent to URLs go through as XML files.

#### Send to email

Use this option if you want the report to always go to a specific e-mail address.

Note: This is less flexible than using Send to Role, since all studies using this report definitions will go to the

#### e-mail address listed

- 1. Click the **Add eMail** button.
- 2. Enter the Name. This can be the recipient?s name or another way to identify the role.
- 3. Enter the email address in the Role/Email Address field.
- 4. If at any time you want to remove information you?ve added, click the Delete button that corresponds to the information you want to remove.

**Send to role** Use this option to always send the report to a role. This offers flexibility, since it will send it to the e-mail address listed for the role for the study using the report definition. This way, if the person(s) listed for the role changes, the report will automatically be sent to the new person in the role.

- 1. Click Add Role.
- 2. Fill in the **Name** field. This can be the recipient?s name or another way to identify the email address.
- 3. Enter the appropriate information in the **Role/Email Address** field.
- 4. If at any time you want to remove information you?ve added, click the **Delete** button that corresponds to the information you want to remove. To add mandatory information, click **Continue**.

#### Send to URL

Use this role for electronic submission of a report. The URL is typically a web service that can consume the report, such as AdEERS.

- 1. Click Add URL.
- 2. Enter the Name. This can be the recipient?s name or another way to identify the URL.
- 3. If the site requires a username and password to access it, enter the information in the **Username** and **Password** fields.
- 4. Enter the **URL**.
- 5. If at any time you want to remove information you?ve added, click the **Delete** button that corresponds to the information you want to remove. To add mandatory information, click **Continue**.

#### 3. Mandatory Fields

The mandatory fields page allows you to select the specific information to be included in the report. The selections are based on the sections of the report, where information is entered into the appropriate fields. The selections available on this page will depend on the Report Format you selected on the previous **Basic Details** page.

• Select **Optional**, **Mandatory** or **Not Applicable** from the drop down lists under each heading. Once you have completed your selections, click **Continue** to add notifications.

**Note:** This page is very long with multiple sections.

#### 4. Notifications

Notifications can be set up to send reminders to people about the report. Multiple reminders can be created for the same report, reminding people that the report is almost due or informing them the report is past due. **Adding a notification** 

- 1. Select the number from the **Time Scale** box. For example, if your report is due on Day 5 (as selected on the Basic Details page), you could select 2 to send a reminder three days before the report is due.
- 2. Add a recipient. Click **Add eMail** and enter an email address or click **Add Role** to select a role from the list. You can add multiple recipients to the notification.

- 3. To add a variable, place your cursor where you want the variable to appear, then select the variable from the **Insert a substitution variable** drop down box.
- 4. Enter a **Subject Line**.
- 5. Type the body of the message in the Message field. To add a variable, place your cursor where you want the variable to appear, then select a variable from the **Insert a substitution variable** drop down box.
- 6. Click **Reset** to clear the information, or **Delete** to completely remove the notification, or **Continue** to review the report.

#### Adding additional notifications for the same time period

You can have multiple notifications sent out for the same Time Period. For example, you could have two different notifications being sent three days before the report is due. To do this, click Add Notification and a second Email notification will appear in the same area.

**Note:** The notifications can be minimized by clicking on the minimize icon.

#### Adding notifications for a different time period

If you want to add a notification for a different time period, for example, the day after the report was due, select a new number from Time Scale box. The notifications you?ve previously created will be saved and the page will only show notifications setup for the new time select. From here, follow the steps described previously for Adding a notification.

#### 5. Review

The Review page allows you to review the Report Definition you?ve created. If the information is correct, click **Save**. If you want to make changes, click **Back** to return to previous sections and made your changes.

## **List Report Definitions**

Click the **Rules tab** and click **List Report Definitions** in the task menu. The list report definition page displays all the report definitions that have been created in caAERS. This page shows some general information about the definition, including the name, description, organization it is for, and when the final report is due.

• To see more information about the report definition, click on the **Name** of the report definition. This will open the definition in create/edit mode.

## **Working with AdEERS**

caAERS is capable of sending AE reports to AdEERS. However, the systems are independent of each other so a platform independent and context-free communication approach was developed. Since AdEERS has already published the necessary WSDLs, the caAERS AdEERS communication infrastructure implements SOAP messaging. In addition, caAERS has infrastructure in place that can handle exceptions returned by AdEERS. These exceptions may be generated due to various reasons, such as:

- The caAERS message being malformed
- A particular job ID not being found

List Report Definitions

#### **Setting up AdEERS communication**

When caAERS is installed, it has all the components necessary to communicate with AdEERS. It simply requires specific information be added during the creation of the following:

- Report Definitions
- Studies
- Expedited Reports

#### **Report Definitions**

AdEERS communication is set up through the report definition tab in caAERS. Existing or new report definitions can be set up for caAERS-AdEERS integration. This is done during the **Report Delivery Details** step of the **Create Report Definition** task. In the **Report Delivery Details** step you need to add the URL of the web server for AdEERS.

• Go to the **Report Delivery Details** section of this guide for step-by-step instructions. If you do not have the URL for the AdEERS web server, contact AdEERS Support.

Note: You should not have any problems if you have a firewall set up.

#### **Studies**

A study can also be defined to require AdEERS reporting. This is setup in the **Details** task page of the **Create Study** process. See the caAERS End User Manual for step-by-step instructions on how to require AdEERS reporting in the Details task page.

#### **Expedited Reports**

Based on the rules set up for the studies, an Expedited Report may prompt you to submit an AdEERS report. If an AdEERS report is not required, you can still manually select to send one. Go to the **Find Out If AEs Require Reporting** section in the caAERS End User Guide for step-by-step instructions.

## **Support**

To get support when you have issues, please check the caAERS Project site, <a href="http://gforge.nci.nih.gov/projects/caaersappdev/">http://gforge.nci.nih.gov/projects/caaersappdev/</a> or contact support at edmond.mulaire@semanticbits.com.

## References

**Technical Articles** 

- Foundations of Object-Relational Mapping: <a href="http://www.chimu.com/publications/objectRelational/">http://www.chimu.com/publications/objectRelational/</a>
- Object-Relational Mapping articles and products: http://www.service-architecture.com/object-relational-mapping/
- Hibernate Reference Documentation: http://www.hibernate.org/hib\_docs/reference/en/html/
- Basic O/R Mapping: http://www.hibernate.org/hib\_docs/reference/en/html/mapping.html
- Java Programming: <a href="http://java.sun.com/learning/new2java/index.html">http://java.sun.com/learning/new2java/index.html</a>
- Javadoc tool: <a href="http://java.sun.com/j2se/javadoc/">http://java.sun.com/j2se/javadoc/</a>

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- Extensible Markup Language: <a href="http://www.w3.org/TR/REC-xml/">http://www.w3.org/TR/REC-xml/</a>
- XML Metadata Interchange: <a href="http://www.omg.org/technology/documents/formal/xmi.htm">http://www.omg.org/technology/documents/formal/xmi.htm</a>

### **Scientific Publications**

- Cancer Therapy Evaluation Program, ?Common Terminology Criteria for Adverse Events, Version 3.0", <a href="http://ctep.cancer.gov/forms/CTCAEv3.pdf">http://ctep.cancer.gov/forms/CTCAEv3.pdf</a>
- Cancer Therapy Evaluation Program, ?Adverse Event Expedited Reporting System (AdEERS)", http://ctep.cancer.gov/forms/CTCAEv3.pdf
- Cancer Therapy Evaluation Program, ?CTEP, NCI Guidelines: Adverse Event Reporting Requirements", <a href="http://ctep.cancer.gov/reporting/newadverse">http://ctep.cancer.gov/reporting/newadverse</a> 2006.pdf
- Division of Cancer Prevention, ?DCP Serious Adverse Event Reporting Procedures and Guidelines, http://dcp.cancer.gov/clinicaltrials/management/consortia/step-3/adverse
- Division of Cancer Prevention, ?DCP Serious Adverse Event Reporting Form, http://dcp.cancer.gov/Files/clinical-trials/sae\_guidelines.doc
- FDA, ?The FDA Safety Information and Adverse Event Program?, http://gforge.nci.nih.gov/projects/ccts/

### caBIG Material

- caBIG: http://cabig.nci.nih.gov/
- caBIG Compatibility Guidelines: http://cabig.nci.nih.gov/guidelines documentation
- caBIG Clinical Trial Suite Project Site: <a href="http://gforge.nci.nih.gov/projects/ccts/">http://gforge.nci.nih.gov/projects/ccts/</a>

### caGrid Material

• caGrid: http://www.cagrid.org/mwiki/index.php?title=CaGrid

## caCORE Material

- caCORE: <a href="http://ncicb.nci.nih.gov/core">http://ncicb.nci.nih.gov/core</a>
- caBIO: http://ncicb.nci.nih.gov/core/caBIO
- caDSR: <a href="http://ncicb.nci.nih.gov/core/caDSR">http://ncicb.nci.nih.gov/core/caDSR</a>
- EVS: http://ncicb.nci.nih.gov/core/EVS
- CSM: http://ncicb.nci.nih.gov/core/CSM

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# Glossary

The following is a list of terms and their definitions that you may find useful as you work with caAERS.

Term	Definition		
AdEERS	Adverse Event Expedited Reporting System		
API	Application Programming Interface		
caArray	cancer Array Informatics		
caBIG	cancer Biomedical Informatics Grid		
caBIO	Cancer Bioinformatics Infrastructure Objects		
caCORE	cancer Common Ontologic Representation Environment		
caDSR	Cancer Data Standards Repository		
caMOD	Cancer Models Database		
cardinality	Cardinality describes the minimum and maximum number of associated objects within a set		
CSM	Common Security Tab		
CTEP	Cancer Therapy Evaluation Program		
CUI	Concept Unique Identifier		
CVS	Concurrent Versions System		
EVS	Enterprise Vocabulary Services		
GAI	CGAP Genetic Annotation Initiative		
HTTP	Hypertext Transfer Protocol		
JDBC	Java Database Connectivity		
JET	Java Emitter Templates		
JMI	Java Metadata Interface		
JSP	JavaServer Pages		
LLT	Lowest Level Term		
MedDRA	Medical Dictionary for Regulatory Activities		
metadata	Definitional data that provides information about or documentation of other data.		
multiplicity	Multiplicity of an association end indicates the number of objects of the class on that end may be associated with a single object of the class on the other end.		
NCI	National Cancer Institute		
NCICB	National Cancer Institute Center for Bioinformatics		
OIL	Ontology Inference Layer		
OilEd	Ontology editor allowing you to build ontologies using DAML+OIL		
PT	Preferred Term		
SQL	Structured Query Language		
SSC	Special Search Categories		
SOAP	Simple Object Access Protocol		
UML	Unified Modeling Language		

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UMLS	Unified Medical Language System		
UPT	User Provisioning Tool		
URL	Uniform Resource Locators		
WSDL	Web Service Descriptive Language		
XML	Extensible Markup Language		

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